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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,267	12/15/2003	Michael Berthon-Jones	3869-020	6196

22440 7590 03/19/2007  
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EXAMINER
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MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

5/18

<b>Office Action Summary</b>	<b>Application No.</b> 10/737,267	<b>Applicant(s)</b> BERTHON-JONES, MICHAEL	
	<b>Examiner</b> Kristen C. Matter	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-48 and 50-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-48 and 50-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08335118.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/30/04 and 12/15/03</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/335,118, filed on 11/4/1994.

Examiner has also requested that an updated filing receipt be mailed to Applicant acknowledging all four claims to priority.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles (US 5,353,788).

Regarding claims 45 and 50, Miles discloses a cardio-respiratory CPAP control system with a pressure transducer for generating an airflow signal representative of respiratory airflow from the patient and a processor (12) for analyzing the signals generated by the transducers (see column 5, lines 1-35). Miles also discloses that the system has ECG leads, which are capable of providing information needed to determine the presence of cardiogenic airflow. Miles does not specifically disclose that the processor has instructions for determining airway patency by detection of cardiogenic airflow. However, the apparatus taught by Miles is structurally the same

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as the claimed invention and is capable of being programmed with instructions for determining airway patency by an analysis to detect cardiogenic airflow **without the installation of additional software**. Please note that the current claim language (i.e., for determining, for generating) is considered intended use and therefore not given patentable weight. The device disclosed by Miles need only have the structural limitations and be capable of performing the intended use.

Regarding claims 51 and 52, the system disclosed by Miles has a means to increase, decrease, or keep unchanged a desired pressure supplied to the patient based on the presence of cardiogenic airflow without the installation of additional software (see column 3, line 63-column 4, line 15).

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles as applied to claim 45 above and further in view of De Vuono et al. (US 4,989,595). Miles is silent as to the CPAP device comprising a turbine. De Vuono et al. discloses a respiratory device with a turbine for supplying pressurized gas to a patient (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Miles's system with a turbine as taught by De Vuono et al. in order to supply the positive pressure to the patient. Furthermore, as mentioned above, the system disclosed by Miles has a means to increase, decrease, or keep unchanged a desired pressure supplied to the patient based on the presence of cardiogenic airflow without the installation of additional software.

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Claims 48, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles as applied to claims 45 and 50 above and further in view of Gruenke et al. (US 5,259,373).

Regarding claims 48 and 53, Miles does not teach a Fourier transform to analyze the measured airflow. Gruenke et al. discloses the use of a Fourier transform to analyze signals from a CPAP device (see Figure 21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a Fourier transform as taught by Gruenke et al. to analyze the airflow signals because Fourier transforms are well known in the art for evaluating frequency components of signals. Furthermore, applicant acknowledges in the disclosure that use of the Fourier transform is not critical, and that any mathematical method of detecting rhythmic oscillation with a frequency of the anticipated heart rate and its first harmonic will suffice.

Regarding claim 54, the apparatus taught by Miles determines patient's cardiac rate and the processor can calculate a component of airflow from this input (see column 4, lines 55-65).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45, 46, and 50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 11 of U.S. Patent No. 6,029,665. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the patented claim and the instant claims are minor and obvious from each other. The instant claim 45 is a broader version of the patented claim 11 (i.e., the instant claim 45 does not include the mask and conduit as in the patented claim 11). In the instant claim 45, the structural limitations are included in the patented claim 11. Any infringement over the patent would also infringe over the instant claim. Hence, the instant claim does not differ from the scope of the patented claim 11. The instant claim 50 is a broader version of the patented claim 7 (i.e., the instant claim 50 does not include the processor means as in the patented claim 7). In the instant claim 50, the structural limitations are included in the patented claim 7. Any infringement over the patent would also infringe over the instant claim. Hence, the instant claim does not differ from the scope of the patented claim 7.

Claims 39-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,029,665 in view of Rapoport (US 5,335,654). Claim 1 of the patented case has everything as claimed including the method steps of measuring respiratory airflow and analyzing the measured airflow to detect the presence of cardiogenic airflow to determine airway patency, but lacks the step of delivering airway treatment pressure based on determination of airway patency. However, Rapoport teaches

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delivering airway treatment pressure based upon a determination of airway patency (see abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the patented claim 1 with the step of delivering airway treatment pressure based upon a determination of airway patency as taught by Rapoport in order to open the airway as needed to treat sleep apnea.

### ***Response to Arguments***

Applicant's arguments, filed 1/11/2007, with respect to the rejection(s) of claim(s) 39-44, have been fully considered and are persuasive. Therefore, the U.S.C. 103(a) rejection has been withdrawn with regard to these method claims.

On the other hand, Applicant's arguments with respect to claims 45-54 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen C. Matter  
Examiner  
Art Unit 3771



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